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10/523,479	09/16/2005	Magdalene M. Moran	110313.138US2	6126
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WILMERHALE/BOSTON			MONTANARI, DAVID A	
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BOSTON, MA 02109			PAPER NUMBER	
			1632	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/523,479

Applicant(s)

MORAN ET AL.

Examiner

David Montanari

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 75-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 75-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's arguments and amendments filed on 8/19/2010 have been entered.
2. The rejection of claim 5 under 35 USC 102(e) is withdrawn in view of Applicant's amendment to the claim.
3. Claims 75-90 are new.
4. Claims 5 and 75-90 are examined in the instant application.

The pending claims are broadly interpreted (as explained in the 112 2nd rejection below) to encompass two different products: 1) an isolated nucleic acid sequence encoding a polypeptide fragment that requires no activity and 2) an isolated nucleic acid sequence encoding a polypeptide fragment that exhibits CatSper3 activity. Because of this interpretation both a written description rejection (applying to product 2) and an art rejection (applying to product 1) are set forth below.

Claim Objections

Claims 75-82 are objected to because of the following informalities: each claim recites either”:

“a CatSper3 protein of SEQ ID NO:” 1 or 3,

“at least a transmembrane domain of a CatSper3 protein of SEQ ID NO:” 1 or 3,

“at least an extracellular loop of a CatSper3 protein of SEQ ID NO:” 1 or 3 or

“at least a pore region of a CatSper3 protein of SEQ ID NO:” 1 or 3.

However, in each of these instances, the claims are referring to protein while referencing either SEQ ID NO: 1 or 3, which are nucleic acid sequences. SEQ ID NOs: 2 and 4 refer to the

amino acid sequences that contain the domain, loop and pore regions above. Applicant can either amend the claims to refer to the proper protein sequences or amend the claims to recite, for example "at least a pore region of CatSper3 protein **encoded by** the nucleotide sequence set forth in SEQ ID NO: 1".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

As discussed below in the 112 2nd rejection, the claims are broadly interpreted to encompass an isolated nucleic acid encoding a polypeptide fragment that exhibits CatSper3 activity in a cell capable of expressing CatSper3 activity. Accordingly, the written description rejection set forth below is applicable over claim 75 and 76 since the encoded polypeptide fragments are required to be functional in activity.

Claims 75 and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

When the claims are analyzed in light of the specification, the instant invention encompasses a fragment encoded by the isolated sequence set forth in SEQ ID NO: 1 or 3. The instant claims each recite that the nucleic acid sequence set forth in SEQ ID NO: 1 or 3 will encode a polypeptide having at least 95% amino acid sequence identity with a CatSper 3 protein encoded by the nucleic acid set forth in SEQ ID NO: 1 (or 3). The "a CatSper3 protein" in line 2

encompasses a fragment and the encoded polypeptide that shares amino acid identity with said fragment is required to have CatSper3 activity in a cell. SEQ ID NO: 1 (full-length human cDNA) and 3 (full-length murine cDNA homolog) are 1203 and 1329 nucleotides in length respectively which encode CatSper3 proteins of 401 and 443 amino acids in size. Since a fragment, for example, of only 10 amino acids is encompassed by the claims (which must also exhibit CatSper3 activity) the claimed isolated nucleic acid encompasses a sequence of 28~29 nucleotides encoding said fragment.

Since the claimed isolated nucleic acids encompass encoding a fragment of the CatSper3 protein which is required to have CatSper3 activity in a cell, the claims lack sufficient written description based upon the teachings the specification and the reasons set forth below.

Regarding function, the claims recite that the isolated sequence will have CatSper3 activity in a cell. However the specification provides no description of any sequences other than the full-length sequences set forth in SEQ ID NO: 1 or 3 that would indicate possession at the time of filing that exhibit CatSper3 activity. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their structure. In the instant case, only SEQ ID NOs: 1 and 3 are sufficiently described to indicate possession of a sequence having CatSper3 activity in a cell. The specification does not provide any disclosure as to what the complete structure would be of any fragmentary nucleic acid sequence, other than the SEQ ID NOs: 1 and 3, disclosed in the specification that would have CatSper3 activity. However the only disclosed sequences that have CatSper3 activity are the sequence set forth in SEQ ID NOs: 1 and 3. There is no general knowledge in the art regarding the CatSper3 activity to suggest that general similarity of

structure confers the activity. The structure and function correlation is not supported by the teachings in the specification. The specification discloses an actual reduction to practice and the complete chemical structure of only SEQ ID NOs: 1 and 3 which also exhibit CatSper3 activity.

Thus, those of ordinary skill in the art would not consider that Applicant to have been in possession of the claimed genus of nucleic acids based on the single species disclosed.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only characteristic described, is that the sequence set forth in SEQ ID NOs: 1 and 3 exhibit CatSper3 activity. The specification does not teach any other identifying characteristics such as domains relating to function/activity or any other related sequences that would guide the artisan to contemplate other nucleic acid sequences that would be encoded by less than the full sequence represented in SEQ ID NOs: 1 and 3. While the specification does teach the location of six transmembrane domains, three extracellular loops and one pore region, the specification has not described or equated how each domain or a fragment thereof would correlate to CatSper3 activity in a cell. The skilled artisan could not rely upon the disclosure in the specification such that the specification would sufficiently describe that Applicant was in possession of any sequence having CatSper3 activity other than the full-length sequences set forth in SEQ ID NOs:1 and 3.

Applicants' attention is directed to the decision in *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, which clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The

invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieve regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the sequences set forth SEQ ID NOs: 1 and 3 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the

invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641,1646 (1998).

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that applicant is in possession of the genus of nucleic acid sequences having CatSper3 activity. However, amending claims 75 and 76 to recite "with the CatSper3 protein of SEQ ID NO: 1 (or 3)" would be remedial.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims 75 and 76 are unclear. Specifically, there appear to be two different products based upon a reading of the claims.

The first product is an isolated nucleic acid encoding a polypeptide fragment wherein said fragment has at least 95% amino acid sequence identity with a CatSper3 protein of SEQ ID NO: 1 or 3, wherein the "CatSper3 protein" recited in line 2 has CatSper3 activity (recited in line 3). Thus the encoded polypeptide fragment does not require CatSper3 activity, only that it has 95% amino acid identity to a CatSper3 protein that does.

The second product is an isolated nucleic acid encoding a polypeptide fragment having at least 95% amino acid sequence identity with a CatSper3 protein of SEQ ID NO: 1 or 3, and has

CatSper3 activity in a cell capable of expressing CatSper3 activity. Thus the polypeptide fragment would exhibit CatSper3 activity.

Simply put, it is not clear if the "CatSper3 protein" recited in line 2 has the activity recited in line 3. If the "CatSper3 protein" in line 2 has activity, then the art rejection below is applicable to the claimed invention, since no activity is required for the encoded polypeptide fragment. If the "CatSper3 protein" in line 2 does not have activity, and thus line 3 refers to activity of the encoded polypeptide fragment then a written description rejection set forth above is applicable.

Applicant in their response is invited to clarify what the activity recited in line 3 refers to, either the CatSper3 protein or the encoded polypeptide fragment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 75-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Haanes et al. (U.S. Patent 6,159,478, issued 12/12/2000).

As discussed above in the 112 2nd rejection, the claims are broadly interpreted to encompass an isolated nucleic acid sequence that encodes a polypeptide fragment that exhibits no CatSper3 activity, thus the claimed invention is drawn to isolated nucleic acid sequences encoding non-functional fragments. Accordingly as set forth below, the teachings of Haanes et

al. would anticipate the claimed invention based upon this interpretation that the encoded fragments are non-functional.

Claim 5 is drawn to an isolated nucleic acid encoding a polypeptide at least 95% amino acid sequence identity with a polypeptide selected from at least a transmembrane domain, at least a pore region and at least an extracellular loop of a CatSper3 protein, wherein said CatSper3 protein is encoded by SEQ ID NO: 1 or 3. Claim 5 is broadly interpreted to encompass a fragment of SEQ ID NO: 1 or 3 since the claimed isolated nucleic acid requires only 95% sequence identity with "a" polypeptide recited from groups a-d. Haanes et al. teach a 22 and a 20 nucleotide sequence that corresponds with SEQ ID NO: 1 and 3 respectively. These nucleotide sequences taught by Haanes encompass the nucleotide sequences recited in claims 75-82 since each claimed sequence only requires 95% identity to "a" sequence encoding a polypeptide having 95% amino acid with a CatSper3 protein.

Claims 83-86 are drawn to an isolated nucleic acid comprising at least 14, 15, 16 and 18 consecutive nucleotides of SEQ ID NO: 1. However, Haanes et al. teach an isolated nucleic acid sequence (SEQ ID NO: 5) comprising 22 consecutive nucleotides of SEQ ID NO: 1
SEQ ID NO: 1 656-TCCTCATCCTCTTCTTCATGCT-677 (Instant)
SEQ ID NO: 5 724-TCCTCATCCTCTTCTTCATGCT-745 (Haanes et al.)

Claims 87-90 are drawn to an isolated nucleic acid comprising at least 14, 15, 16 and 18 consecutive nucleotides that encode a portion of SEQ ID NO: 3. However, Haanes et al. teach an isolated nucleic acid sequence (SEQ ID NO: 1) comprising 20 consecutive nucleotides of instant SEQ ID NO: 1.
SEQ ID NO: 1 586-CTCATCCTCTTCTTCATGCT-605 (Instant)

SEQ ID NO: 1 1539-CTCATCCTCTTCTTCATGCT-1520 (Haanes et al.)

Thus the teachings of Haanes et al. clearly anticipate the inventions of claims 5 and 75-90.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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